



August 31, 2000

Sally Van Wert, Ph. D.
Aventis CropScience
P.O. Box 12014
2 T W. Alexander Drive
Research Triangle Park, NC 27709

Dear Dr. Van Wert:

This is in regard to Aventis CropScience's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center of Food Safety and Applied Nutrition) on its genetically modified LLRICE06 and LLRICE62 glufosinate-ammonium tolerant rice (also called "Liberty Link®" rice). According to Aventis CropScience, this new line is modified for herbicide tolerance through the expression of the *bar* gene from *Streptomyces hygroscopicus*. The *bar* gene encodes the phosphinothricin-N-acetyl transferase, which catalyzes the conversion of L-phosphinothricin (the active ingredient of the herbicide "glufosinate-ammonium" into an inactive form.

As part of bringing the consultation regarding this product to closure, Aventis submitted a summary of its safety and nutritional assessment of the genetically modified LLRICE06 and LLRICE62 Liberty Link rice on November 30, 1999, and submitted supplementary information on August 4, 2000. These communications informed the FDA of the steps taken by Aventis to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Aventis has conducted, it is our understanding that Aventis has concluded that rice grain, straw, and processed fractions (which include rice hulls, brown rice, parboiled brown rice, polished rice, rice flour, rice bran, and bran oil) derived from the new variety, are not materially different in composition, safety, and other relevant parameters from rice grain, straw, and processed rice fractions currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF 0063. This file will be maintained in the Office of Premarket Approval.

Based on the information Aventis CropScience has presented to FDA, we have no further questions concerning rice grain, straw, and processed fractions derived from the "Liberty Link®" LLRICE06 and LLRICE62 rice at this time. However, as you are aware, it is Aventis

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CropScience's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.

Director

Office of Premarket Approval

Center for Food Safety

and Applied Nutrition